

13. (Amended) The process of claim 1, wherein the initiator is ionization radiation.

14. (Amended) The process of claim 1, wherein the initiator is a chemical catalyst.

REMARKS

Claims 1-9 and 11-48 are pending. Claims 47-48 are allowed.

In response to the Office Action dated September 5, 2002, each one of the cited references has been reviewed, and the rejections and objections made to the claims by the Examiner have been considered. Applicants have traversed all rejections and objections regarding all pending claims, and therefore allowance of these claims is earnestly solicited.

REJECTIONS UNDER 35 USC §102(B)

Claims 1-3, 5, 7-9 and 17-20

The Examiner has rejected claims 1-3, 5, 7-9 and 17-20 under 35 USC §102(b) as being anticipated by Hoffman et al (USPN 3,826,678). The Examiner states that Hoffman teaches a method of preparing biocompatible and biofunctional materials by radiation grafting a reactable compound onto an inert polymeric substrate and thereafter chemically bonding a biologically active molecule such as heparin.

In response, Applicants submit that the rejection has been traversed by the foregoing arguments. While the Hoffman reference may teach a method for preparing biocomparable and biofunctional materials, Hoffman does not anticipate the methods of the present invention. More specifically, Hoffman teaches methods of radiation grafting reactable compounds (polymers and copolymers) onto an inert surface and subsequently covalently attaching biologically active compounds to the reactable compounds (see abstract). Because the inert surface lacks reactive binding sites, radiation energy (see col. 4, lines 1-3) is used to form reactive sites so as to covalently bind the reactable compounds to an inert surface.

In sharp contrast, the methods of the present invention do not utilize radiation grafting to covalently bind the monomers to the surface of a polymer substrate. Rather, according to the methods of the present invention, the surface of the polymer substrate

is swollen thereby allowing the absorption of the monomers. As a result, indirect bonding between the monomers and the polymer substrate can be achieved(see specification, p. 6, lines 14-19). That is, catenary connection and other forms of chain entanglement are responsible for the indirect bonding of the monomer and the polymer substrate. (The catenary connection and chain entanglement is illustrated in FIG. 2 whereas prior art techniques of covalent bonding are illustrated in FIG.1.) Because the Hoffman reference does not disclose that the monomers may be indirectly bonded to the surface of the polymer substrate, Applicants respectfully submit that the methods of the present invention are not anticipated by Hoffman. Accordingly, Applicants respectfully request the allowance of claims 1-3, 5, 7-9 and 17-20.

Claims 1-9, 17-19, 21-23, 25, 27-29, 37-39, and 41-46

The Examiner has rejected claims 1-9, 17-19, 21-23, 25, 27-29, 37-39, and 41-46 under 35 USC §102(b) as being anticipated by Goldberg (USPN 5,290,548). The Examiner asserts that Goldberg teaches method of modifying a surface by chemically grafting a plastic substrate with (1) a neutral or ionic water soluable hydrophilic vinylic monomer or salt thereof, (2) a mixture of at least two monomers, or a mixture of (1) or (2) with up to 50% by weight of a compound selected from N-vinyl pyrrolidone 2-hydroxyethylmethacrylate.

In response, Applicants respectfully submit that the Goldberg reference does not anticipate the methods of the present invention as recited in the amended claims. More specifically, Goldberg does not teach a method of modifying a surface of a polymer substrate by absorbing a swelling monomer into the polymer substrate and then polymerizing the monomer with an initiator. Because Goldberg fails to disclose polymerization with an initiator, it is respectfully submitted that the rejection is unsupported by the art and should be withdrawn.

REJECTIONS UNDER 35 USC §102(E)

The Examiner has rejected claims 1-19, 21-39, and 41-46 as being anticipated by Ottersbach et al (USPN 6,001,894). In response, Applicants respectfully submit that the rejection is improper as Ottersbach fails to teach that the swelling monomers are absorbed by the polymer substrate. That is, Ottersbach teaches a process of graft polymerization. Graft polymerization is process wherein the surface is activated so that

reactive centers are created on the surface of the substrate which serve as starting points of the actual polymerization as the reaction proceeds (see col. 1, lines 31-41). That is, the methods as disclosed in Ottersbach covalently bond the monomer to the surface of the polymer substrate. In sharp contrast, the present invention does not covalently bond the monomer to the surface of the polymer substrate. Rather, as previously asserted, the swelling monomers are absorbed on the surface of the polymer substrate. Accordingly, because the Otterbach reference fails to teach the absorption of the monomers on the polymer substrate, Applicants respectfully submit that the rejection is unsupported by the Ottersbach reference and should be withdrawn.

REJECTIONS UNDER 35 USC §103(A)

The Examiner has rejected claims 20 and 40 under 35 USC §103(a) as being unpatentable over Ottersbach. The Examiner notes that "Ottersbach fails to expressly teach adhering heparin to the surface of a polymeric substrate." The Examiner contends that "it would have been obvious for one of ordinary skill in the art to adhere heparin, an anti-coagulant for blood, to the surface of the modified polymeric substrates by the Ottersbach method when used in medical applications." The Examiner states that the "motivation would have been the adequate prevention of the blood clotting in/on the medical products produced by the Ottersbach method in the absence of unexpected results and arguments to the contrary."

In response, it is respectfully submitted that the Examiner has not established a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. See MPEP §2142, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The initial burden is on the Examiner to provide some suggestion of the desirability of doing what is the inventor has done. "To support the conclusion the

claimed invention is directed to obvious subject matter, either the references expressly or implicitly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why an artisan would have found the claimed invention to have been obvious in light of the teachings of the references." See MPEP §2142, Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App.& Inter. 1985).

More specifically, the Examiner has failed to demonstrate the suggestion or motivation in Ottersbach to provide anti-coagulants such as heparin on the surface of a polymeric substrate. Nowhere does Ottersbach suggest that anti-coagulation was a problem to be solved. Rather, Ottersbach discloses that the coating of Ottersbach is useful for hygiene products to act as dirt-repellants or bacterial repellants. Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, and respectfully request the withdrawal of the rejection.

Moreover, the Examiner has incorrectly placed the burden on the Applicants to demonstrate that the "motivation would have been the adequate prevention of the blood clotting in/on the medical products produced by the Ottersbach method *in the absence of unexpected results and arguments to the contrary*" (emphasis added). As noted in MPEP §2142, the Examiner bears the initial burden of *factually supporting* any *prima facie* case of obviousness (emphasis added). Applicants submit that the Examiner has not provided any factual support that would motivate a person of ordinary skill in the art to apply heparin to the surface of the substrate. Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, and respectfully request the withdrawal of the rejection.

Additionally, the Applicants submit that the Ottersbach reference does not disclose all the claim limitations of the claims 20 and 40. As previously asserted, the Applicants submit that Ottersbach fails to anticipate the methods of the present invention as recited in claims 20 and 40. Because Ottersbach fails to anticipate the independent claims, it is submitted that the Ottersbach reference can not render dependent claims 20 and 40 as obvious as all the claim limitations of the present invention are not disclosed in the Ottersbach reference. Thus, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, and respectfully request the withdrawal of the rejection.

CONCLUSION

Claims 1-9 and 11-48 are pending.

In view of the above remarks and amendments, it is submitted that the pending claims are in condition for allowance and their allowance is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

If any issues remain, the Examiner is urged to contact the undersigned by telephone for a prompt resolution thereof.

No additional fees are seen as being necessary in connection for this amendment. However, the Examiner is authorized to charge any additional fees or credit any overpayment to Deposit Account 50-1901.

Respectfully submitted,



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Version with markings to show changes made

Please amend claims 1 and 11-14 as follows:

1. (Amended) A process for the surface modification of a polymer substrate, the process comprising the steps of:
 - a. absorbing a swelling monomer into the polymer substrate in order to swell the polymer substrate;
 - b. polymerizing the swelling monomer for a period of time, wherein an initiator initiates the polymerization of the swelling monomer; and
 - c. removing the polymer substrate from the swelling monomer at the end of the period of time.
11. (Amended) The process of claim [10] 1, wherein the initiator is ultraviolet radiation.
12. (Amended) The process of claim [10] 1, wherein the initiator is heat.
13. (Amended) The process of claim [10] 1, wherein the initiator is ionization radiation.
14. (Amended) The process of claim [10] 1, wherein the initiator is a chemical catalyst.